

Serial No.: 09/807,657  
Group Art Unit No.: 1648

**In the Claims:**

Claims 1-31 (Cancelled).

32. (Currently Amended) An adjuvant composition comprising an immunostimulant adsorbed onto a metallic salt particle, wherein the metallic salt particle is substantially free of antigen and wherein the immunostimulant is selected from the group consisting of monophosphoryl lipid A, derivatives thereof, an immunostimulatory nucleotide, and an immunostimulatory cytokine. ~~not a saponin derived from the bark of Quillaja Saponaria Molina.~~

33. (Currently Amended) ~~An~~ The adjuvant composition ~~as claimed in~~ of claim 32, wherein the metallic salt particle is a salt of ~~aluminium~~ aluminum, zinc, calcium, cerium, chromium, iron, or ~~berilium~~ beryllium.

34. (Currently Amended) ~~An~~ The adjuvant composition ~~as claimed in~~ of claim 32, wherein the metallic salt is a phosphate or hydroxide.

35. (Currently Amended) ~~An~~ The adjuvant composition ~~as claimed in~~ of claim 32, wherein the metallic salt is ~~aluminium~~ aluminum hydroxide or ~~aluminium~~ aluminum phosphate.

36. (Currently Amended) ~~An~~ The adjuvant composition ~~as claimed in~~ of claim 32, wherein the immunostimulant is monophosphoryl lipid A or a derivative thereof.

37. (Currently Amended) ~~An~~ The adjuvant composition ~~as claimed in~~ of claim 36, wherein the derivative of monophosphoryl lipid A is 3-de-O-acylated monophosphoryl lipid A.

38. (Cancelled).

39. (Currently Amended) A process for the manufacture of a vaccine composition comprising ~~the admixture of~~ admixing a) an adjuvant composition ~~comprising~~ containing an immunostimulant adsorbed onto a first metallic salt particle substantially free of antigen, and b) an antigen.

Serial No.: 09/807,657  
Group Art Unit No.: 1648

40. (Currently Amended) The process of ~~A process for the manufacture of a vaccine composition as claimed in~~ claim 39, wherein the antigen is adsorbed onto a second metallic salt particle substantially free of antigen, wherein the metallic salt of each of the first metallic salt particle and the second metallic salt particle may be the same.
41. (Currently Amended) A process for the manufacture of an immunogenic composition comprising ~~the admixture of~~ admixing a) an adjuvant composition ~~comprising~~ containing an immunostimulant adsorbed onto a first metallic salt particle substantially free of antigen, and b) an antigen, wherein the antigen of b) elicits an immune response to a pathogen, polypeptide, or anti-tumour antigen selected from the group ~~comprising~~ consisting of antigens derived from Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex Virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, IgE peptides, Der p1, pollen related antigens; or Tumor associated antigens (TAA), MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, KSA, and PRAME.
42. (Currently Amended) A vaccine composition comprising an adjuvant composition ~~according to any one of claims 32 to 37, additionally comprising~~ and an antigen, wherein the adjuvant composition contains an immunostimulant adsorbed onto a metallic salt particle, wherein the metallic salt particle is substantially free of the antigen and wherein the immunostimulant is selected from the group consisting of monophosphoryl lipid A, derivatives thereof, an immunostimulatory nucleotide, and an immunostimulatory cytokine.
43. (Cancelled)
44. (Currently Amended) A vaccine comprising a saponin adsorbed onto a metallic salt particle wherein the vaccine ~~comprises~~ contains an antigen, ~~characterised in that~~ and wherein the metallic salt particle is substantially free of ~~said~~ the antigen.

Serial No.: 09/807,657  
Group Art Unit No.: 1648

45. (Currently Amended) ~~A~~ The vaccine according to ~~of~~ claim 44, wherein the saponin is QS21.

46. (Currently Amended) A vaccine composition comprising two major populations of complexes, (a) a first complex comprising containing (a) an immunostimulant adsorbed onto a metallic salt particle, characterised in that said metallic salt particle which is substantially free of antigen; and (b) a second complex comprising containing (b) antigen adsorbed onto a metallic salt particle which is optionally substantially free of immunostimulant; wherein the metallic salt from the first complex may be identical to or different from the metallic salt of the second complex.

47. (Cancelled)

48. (Currently Amended) ~~A~~ The vaccine composition as claimed in ~~of~~ claims 46 ~~or~~ 47, wherein the metallic salt present in the first and second complexes are identical.

49. (Currently Amended) ~~A~~ The vaccine composition as claimed in claims ~~of claim~~ 46 ~~or~~ 47, wherein the second complex ~~comprises~~ contains a plurality of sub-complexes, each sub-complex ~~comprising containing~~ a different an antigen adsorbed onto a metallic salt particle wherein each sub-complex contains a different antigen.

50. (Currently Amended) ~~A~~ The vaccine composition as claimed in any one of claims 44 to 47 of claim 44, wherein the metallic salt is a salt of ~~aluminium~~ aluminum, zinc, calcium, cerium, chromium, iron, or ~~berilium~~ beryllium.

51. (Currently Amended) ~~A~~ The vaccine composition as claimed in ~~of~~ claim 50 wherein the metallic salt is a phosphate or hydroxide.

52. (Currently Amended) ~~A~~ The vaccine composition as claimed in ~~of~~ claim 51 wherein the metallic salt is aluminium hydroxide or aluminium phosphate.

53. (Currently Amended) ~~A~~ The vaccine composition as claimed in ~~of~~ claim 42, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

54. (Cancelled)

Serial No.: 09/807,657  
Group Art Unit No.: 1648

55. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 45, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

56. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 46, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

57. (Cancelled)

58. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 48, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

59. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 49, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

60. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 50, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

61. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 51, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

62. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 52, wherein the immunostimulant is 3-de-O-acylated monophosphoryl lipid A.

Claims 63-70. (Cancelled).

71. (Currently Amended) ~~An~~ The immunogenic composition ~~as claimed in~~ of claim 127, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA,

Serial No.: 09/807,657  
Group Art Unit No.: 1648

PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequesterin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* spp.

72. (Cancelled)

73. (Currently Amended) ~~An~~ The immunogenic composition ~~as claimed in~~ of claim 129, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequesterin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* spp.

74. (Currently Amended) ~~An~~ The immunogenic composition ~~as claimed in~~ of claim 130, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour

Serial No.: 09/807,657  
Group Art Unit No.: 1648

antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* spp.

75. (Currently Amended) ~~An~~ The immunogenic composition ~~as claimed in~~ of claim 131, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa,

Serial No.: 09/807,657  
Group Art Unit No.: 1648

*P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

76. (Currently Amended) ~~An~~ The immunogenic composition of claim 132, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone)(~~LHRH~~(~~GnRH~~), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

77. (Currently Amended) ~~An~~ The immunogenic composition of claim 133, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen

Serial No.: 09/807,657

Group Art Unit No.: 1648

related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* spp.

78. (Currently Amended) ~~An~~ The immunogenic composition ~~as claimed in~~ of claim 134, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* spp.



79. (Currently Amended) ~~An~~ The immunogenic composition as ~~claimed in~~ of claim 135, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B (“Hib”), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, ~~and~~ PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

80. (Currently Amended) ~~An~~ The immunogenic composition as claimed in claim 136, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B (“Hib”), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum*

Serial No.: 09/807,657  
Group Art Unit No.: 1648

RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

81. (Currently Amended) ~~A~~ The immunogenic composition ~~as claimed in~~ of claim 137, wherein the antigen elicits an immune response against a pathogen, polypeptide, or anti-tumour antigen selected from the group consisting of: Human Immunodeficiency Virus, Varicella Zoster virus, Herpes Simplex Virus type 1, Herpes Simplex virus type 2, Human cytomegalovirus, Dengue virus, Hepatitis A, B, C or E, Respiratory Syncytial virus, Human papilloma virus, Influenza virus, *Haemophilus influenzae* Type B ("Hib"), Meningitis virus, Salmonella, Neisseria, Borrelia, Chlamydia, Bordetella, Plasmodium or Toxoplasma, stanworth decapeptide, Der p1, pollen related antigens; or cancer associated antigens, MAGE, BAGE, GAGE, MUC-1, Her-2 neu, luteinizing hormone-releasing hormone (gonadotropin-releasing hormone), CEA, PSA, tyrosinase, Survivin, KSA, PRAME, RTS,S, *P. faciparum* MSP1, *P. faciparum* AMA1, *P. faciparum* MSP3, *P. faciparum* EBA, *P. faciparum* GLURP, *P. faciparum* RAP1, *P. faciparum* RAP2, *P. faciparum* Sequestrin, *P. faciparum* PfEMP1, *P. faciparum* Pf332, *P. faciparum* LSA1, *P. faciparum* LSA3, *P. faciparum* STARP, *P. faciparum* SALSA, *P. faciparum* PfEXPa, *P. faciparum* Pfs25, *P. faciparum* Pfs28, *P. faciparum* PFS27/25, *P. faciparum* Pfs16, *P. faciparum* Pfs48/45, *P. faciparum* Pfs230, and any analogues of *P. faciparum* antigens from *Plasmodium* ssp.

82. (Currently Amended) ~~A~~ The vaccine composition ~~as claimed in~~ of claim 42, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

83. (Cancelled)

Serial No.: 09/807,657  
Group Art Unit No.: 1648

84. (Currently Amended) A The vaccine composition ~~as claimed in claim~~ of claim 44, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

85. (Currently Amended) A The vaccine composition ~~as claimed in claim~~ of 45, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

86. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 46, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

87. (Cancelled)

88. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 48, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

89. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 49, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

90. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 50, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

91. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 51, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

92. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 52, wherein the antigen is a combination of Hepatitis A antigen and Hepatitis B antigen.

93. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 42, wherein the antigen is RTS,S.

Serial No.: 09/807,657  
Group Art Unit No.: 1648

94. (Cancelled)
95. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 44, wherein the antigen is RTS,S.
96. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 45, wherein the antigen is RTS,S.
97. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 46, wherein the antigen is RTS,S.
98. (Cancelled)
99. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 48, wherein the antigen is RTS,S.
100. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 49, wherein the antigen is RTS,S.
101. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 50, wherein the antigen is RTS,S.
102. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 51, wherein the antigen is RTS,S.
103. (Currently Amended) A The vaccine composition ~~as claimed in~~ of claim 52, wherein the antigen is RTS,S.
104. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 42.

Serial No.: 09/807,657  
Group Art Unit No.: 1648

105. (Cancelled)

106. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 44.

107. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 45.

108. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 46.

109. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 47.

110. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 48.

111. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 49.

Serial No.: 09/807,657  
Group Art Unit No.: 1648

112. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 50.

113. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 51.

114. (Currently Amended) A method of treating a mammal suffering from or susceptible to a pathogenic infection, or cancer, or allergy, comprising the administration of a safe and effective amount of a the vaccine composition ~~according to~~ of claim 52.

115. (Previously Presented) A kit comprising two containers, one container having monophosphoryl lipid A, or derivative thereof, adsorbed onto a metallic salt; and the second container having antigen adsorbed onto a metallic salt.

116. (Currently Amended) ~~An~~ A vaccine composition comprising: a) an immunostimulant adsorbed onto a metallic salt particle, wherein the immunostimulant is selected from the group consisting of bacterially derived compounds, monophosphoryl lipid A, immunostimulatory oligonucleotides, CpG, block copolymers, cholera toxin, immunostimulatory cytokines, GM-CSF, IL-1, polyriboA, polyriboU, and Muramyl tripeptide, and b) an antigen, wherein the antigen is not adsorbed onto the metallic salt particle.

117. (Cancelled).

118. (Cancelled)

119. (Cancelled)

Serial No.: 09/807,657  
Group Art Unit No.: 1648

120. (Currently Amended) ~~The A process as claimed in~~ of claim 41, wherein the antigen elicits an immune response to human papilloma virus (HPV).

121. (Currently Amended) The process ~~according to~~ of claim 120, wherein the HPV is selected from the group consisting of: HPV 6, HPV 11, HPV 16 and HPV 18.

122. (Currently Amended) The process ~~according to~~ of claim 120, wherein the antigen is an L1 particle or capsomer.

123. (Currently Amended) ~~The A vaccine composition accordingly~~ of to claim 42 wherein the antigen elicits an immune response to human papilloma virus (HPV).

124. (Currently Amended) The vaccine composition according to claim 123, wherein the HPV is selected from the group of: HPV 6, HPV 11, HPV 16 and HPV 18.

125. (Previously Presented) ~~The A vaccine composition according to~~ of claim 123, wherein the antigen is an L1 particle or capsomer.

126. (Cancelled)

127. (Currently Amended) An immunogenic composition comprising an adjuvant composition ~~according to any one of claims 32 to 37, additionally comprising an antigen, wherein the adjuvant composition contains an immunostimulant adsorbed onto a metallic salt particle, wherein the metallic salt particle is substantially free of the antigen and wherein the immunostimulant is selected from the group consisting of monophosphoryl lipid A, derivatives thereof, an immunostimulatory nucleotide, and an immunostimulatory cytokine..~~

128. (Cancelled)

Serial No.: 09/807,657  
Group Art Unit No.: 1648

129. (Currently Amended) An immunogenic composition comprising a saponin adsorbed onto a metallic salt particle wherein the composition ~~comprises~~ contains an antigen, ~~characterised in that and wherein~~ the metallic salt particle is substantially free of adsorbed antigen.

130. (Currently Amended) ~~The An~~ immunogenic composition ~~according to~~ of claim 129, wherein the saponin is QS21.

131. (Currently Amended) An immunogenic composition comprising two populations of complexes, a first complex comprising, (a) a first complex comprising containing (a) an immunostimulant adsorbed onto a metallic salt particle, ~~characterised in that said metallic salt particle which~~ is substantially free of antigen; and (b) a second complex comprising containing (b) antigen adsorbed onto a metallic salt particle which is optionally substantially free of immunostimulant; wherein the metallic salt from the first complex may be identical to or different from the metallic salt of the second complex.

132. (Cancelled)

133. (Currently Amended) ~~The An~~ immunogenic composition ~~as claimed in claims of claim 131 or 132~~, wherein the metallic salt present in the first complex is identical to the metallic salt present in the second complex.

134. (Currently Amended) ~~The An~~ immunogenic composition ~~as claimed in claims of claim 131 or 47~~, wherein the second complex ~~comprises~~ contains a plurality of sub-complexes, each sub-complex ~~comprising containing a different an~~ antigen adsorbed onto a metallic salt particle wherein each sub-complex contains a different antigen.



135. (Currently Amended) ~~The An~~ immunogenic composition ~~as claimed in any one of claims 129 to 132~~, wherein the metallic salt is a salt of aluminum ~~aluminium~~, zinc, calcium, cerium, chromium, iron, or beryllium ~~berilium~~.

136. (Currently Amended) ~~The An~~ immunogenic composition ~~of as claimed in~~ claim 135 wherein the metallic salt is a phosphate or hydroxide.

137. (Currently Amended) ~~The An~~ immunogenic composition ~~as claimed in~~ of claim 136 wherein the metallic salt is aluminium hydroxide or aluminium phosphate.

138. (Previously Presented) An adjuvant composition comprising an immunostimulant adsorbed onto a metallic salt particle, wherein the metallic salt particle is substantially free of antigen and wherein the immunostimulant is selected from the group consisting of: bacterial derived compound, immunostimulatory oligonucleotide, block copolymer, cholera toxin, and immunostimulatory cytokine.

139. (Previously Presented) The adjuvant composition of claim 138 wherein the bacterial derived compound is selected from the group consisting of: Monophosphoryl lipid A and 3 De-O-acylated monophosphoryl lipid A.

140. (Previously Presented) The adjuvant composition of claim 138 wherein the immunostimulatory oligonucleotide is selected from the group consisting of:

CpG,  
TCC ATG AGC TTC CTG ACG TT,  
TCT CCC AGC GTG CGC CAT, and  
TCG TCG TTT TGT CGT TTT GTC GTT.

141. (Previously Presented) The adjuvant composition of claim 138 wherein the immunostimulatory cytokine is selected from the group consisting of: GM-CSF, IL-1, polyriboA, polyriboU, and Muramyl tripeptide.